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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,114	11/13/2001	Raymond H. Boutin	AHP1CUSA	5743
38199	7590	09/22/2004	EXAMINER	
HOWSON AND HOWSON CATHY A. KODROFF ONE SPRING HOUSE CORPORATE CENTER BOX 457 SPRING HOUSE, PA 19477			CROUCH, DEBORAH	
			ART UNIT	PAPER NUMBER
			1632	
DATE MAILED: 09/22/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/010,114

Applicant(s)

BOUTIN, RAYMOND H.

Examiner

Deborah Crouch, Ph.D.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2004 and 05 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 17-52 is/are pending in the application.
- 4a) Of the above claim(s) 3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-9 and 17-52 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1632

Applicant's comments filed June 30, 2004 are noted.

The amendment filed March 5, 2004 has been entered. Claim 49 replaces claim 3 as the claim elected for examination. Thus, claim 3 is withdrawn from further consideration as it no longer contains the elected subject matter.

Pending claims are 1-9 and 17-52. Claim 3 is withdrawn. Claims 1, 2, 4-9 and 17-52 are examined in this office action.

Applicant is advised that the petition to claim priority has been granted. IF PAIRS does not reflect the correct priority date, applicant may contact the examiner or OIPE.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 5-9 and 17-52 rejected under 35 U.S.C 112, first paragraph, because the specification, while being enabling for methods for the transfer of a nucleic acid composition to cells in culture comprising introducing a multifunctional molecular complex to cells where the complex comprises a nucleic acid encoding a therapeutic protein or polypeptide and a transfer moiety, does not reasonably provide enablement to methods for the nuclear transfer of a nucleic acid composition to cells in vivo comprising introducing a multifunctional molecular complex to cells where the complex comprises a nucleic acid encoding a therapeutic protein or polypeptide and a transfer moiety.

The examiner would agree that the claims are enabled for methods of transfer where the target cells are cultured cells. However, the examiner does not find the claimed methods are enabled for methods of transfer where the target cells are contained within a body or in vivo. The in vivo aspect of claims 1,2, 5-9 and 17-52 is

Art Unit: 1632

interpreted as gene therapy as the specification does not disclose a use for delivering a therapeutic protein other than for therapeutic purposes (see specification, page 3, lines 9-13; page 39, lines 15-19 and 24-32; and page 40, line 34 to page 41, line 2).

As applicant has broadly disclosed treatment of any disease and emphasized hyperproliferative diseases, but stated no specific diseases, the examiner believes that the general teachings in the art of gene therapy and cancer gene therapy at the time of filing are appropriate in summarizing the state of the art at the time of effective filing date, September 28, 1994.

Applicant argues that there is no requirement in either the specification or the claims that the transfer be to the nucleus of a cell. Applicant argues that this is an improper rejection based on language which is not recited nor a claim limitation. Applicant argues that they have shown introduction of the multifunctional molecular complexes into a variety of cells types. Applicant argues that their claims are not limited to a nucleic acid composition that encodes a peptide or protein. Applicant argues that the encoded peptides or proteins may also be used for variety of different purposes. Applicant argues that the Schauer declaration demonstrates that the multifunctional molecular complexes deliver a nucleic acid sequence in vivo and induces an immune response. These arguments are not persuasive.

The multifunctional molecular complex would necessarily have to deliver the complexed nucleic acid to the nucleus of a target cell, either in directly or directly, for transcription to occur. There can be no protein production without first mRNA production, which occurs in the nucleus. Further, applicant elected group I, the nucleic acid encoding therapeutic agents. Nucleic acids encoding other proteins or peptides such as vaccines or fungicides, are not being examined. A therapeutic agent is to be delivered by the claimed method, thus the methods are directed to gene therapy; there is no other reason do deliver a therapeutic agent. The Schauer

Art Unit: 1632

declaration demonstrates a humoral and CTL response to a multifunctional molecular complex comprising a nucleic acid encoding HSV gD. This protein is not a therapeutic protein, it is an immunogen. The Schauer declaration at paragraphs 10-14 thus are directed to vaccine methods. The Schauer declaration at paragraphs 7-10 are to direct to cell delivery.

Claim 4 would allowable if written in conformance with the election.

Claims 1-9 and 17-48 are free of the art. At the time of filing the prior art did not teach or suggest methods of transfer using a transfer moiety of the claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0408. The fax

Art Unit: 1632

phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

September 20, 2004